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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/956,991 10/23/97 KORENBERG

J P-CE-2817

EXAMINER

HM22/0725

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ART UNIT PAPER NUMBER

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/956,991	Applicant(s) Korenberg
	Examiner Mary B. Tung	Art Unit 1644

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on May 8, 2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 835 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1, 11, 13-19, 21-29, and 31-49 is/are pending in the application.

4a) Of the above, claim(s) 11, 13-19, and 21-29 is/are withdrawn from consideration.

5) Claim(s) 44-46 is/are allowed.

6) Claim(s) 1, 31-43, and 47-49 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) Other: _____

DETAILED ACTION

Claims 1-30 were originally elected.

Claims 2-10, 12, 20 and 30 were cancelled in the paper filed 2/16/00, Paper No. 17.

Claims 31-49 were added in Paper No. 17.

Claims 11, 13-19 and 21-29 stand withdrawn as being drawn to a non-elected invention.

Claims 1 and 31-49 are under consideration.

Request for Continued Examination

1. A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's submission filed on 11/8/2000, Paper No. 20, has been entered.

Claim Rejections - 35 U.S.C. § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Applicant for a patent.
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Applicant's arguments filed in Paper No. 20 have been fully considered but they are not persuasive.

4. Claim 1 stands rejected under 35 U.S.C. 102(a) as being anticipated by Korenberg, et al. (*PNAS USA, 91;4997-5001, 1994*), for the same reasons set forth in the action mailed 8/16/99, Paper No. 18.

5. The Applicants argue that Korenberg, et al. do not teach the claimed invention since "none of the claimed nucleic acid molecules were isolated or purified away from the rest of the genes in the genomic DNA sample." [underlining added by Applicants for emphasis] Additionally, the Applicants assert that "the isolated nucleic acid molecules

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of the invention exclude all the other genes and nucleic acids in the genome except the claimed nucleic acid molecules. The Examiner respectfully directs the Applicants' attention to the wording of claim 1 that recites a nucleic acid molecule *comprising* the claimed sequences. Since "comprising" is open language, the Examiner maintains that the recitation of claim 1 would be encompassed by the reference teaching and therefore, the rejection stands.

6. Claims 33-35, 38 and 41 are rejected under 35 U.S.C. 102(a) as being anticipated by Korenberg, et al. (*PNAS USA*, 91:4997-5001, 1994).
7. Korenberg, et al. teach an isolated nucleic acid obtained from patients with Down Syndrome (see the abstract and page 4997, col. 1, last paragraph and bridging over to page 4998, col. 1). DS-CAM would inherently be encoded by nucleic acid taught by Korenberg, et al., absent evidence to the contrary. The isolated chromosomal DNA isolated for Southern blot analysis, as taught on page 4998 would also be expected to hybridize to SEQ ID NO: 1 under the recited conditions, absent evidence to the contrary. Claims 33 and 35 are included because of the high homology among the sequences identified as SEQ ID NOS: 1, 7, 8, 9 and 10, which encodes SEQ ID NO: 11, as recited in claim 33, one would expect hybridization of said sequences under the claimed conditions, absent evidence to the contrary.
8. The Applicants arguments concerning Korenberg, et al. are discussed *supra*.
9. Claims 33-37, 47 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Genexpress cDNA Program (*GenBank*, Accession # F13426).
10. The F13426 sequence listing teaches a 309 bp fragment of nucleic acid which encodes a 103 amino acid fragment of SEQ ID NO: 2. The F13426 sequence listing teaches that the sequence fragment has a 95.1% identity with the nucleic acid sequence that encodes SEQ ID NO:2. The F13426 sequence listing also teaches the cDNA, as recited in claim 47 was cloned into a *lafmid BA* vector and a mRNA sequence, as recited in claim 48. Claims 36 and 37 are included because the *lafmid BA* vector was derived from the pEMBL vector, which is an *E. coli* to yeast shuttle plasmid vector and thus requires a host (recombinant) cell for storage and shipment as evidenced by ATCC Catalog No. 37395. Claims 33 and 35 are included because of the high homology among the sequences identified as SEQ ID NOS: 1, 7, 8, 9 and 10, which encodes SEQ ID NO: 11, as recited in claim 33, one would expect hybridization of said sequences under the claimed conditions, absent evidence to the contrary.
11. The Applicants argue that the F13426 sequence corresponds to a segment of SEQ ID NO: which encodes a small portion of the cytoplasmic domain, which is absent in SEQ

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ID NO: 11. The Examiner invites the Applicant to provide support for this assertion to overcome this rejection.

Claim Rejections - 35 U.S.C. § 103

12. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under *subsection (f) or (g)* of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

13. Claims 1, 31-43 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korenberg, et al. (*PNAS USA, 91:4997-5001, 1994*), in view of Gallatin, et al., (US Patent No. 5,525,487).

14. Korenberg has been discussed, *supra*. Korenberg does not teach or a method for expression of a DS-CAM related protein. However, the '487 patent teaches that in order to produce the polypeptide in large quantities, host cells transfected with a vector comprising a nucleic acid, can be used in a method of expressing the polypeptide then isolating the polypeptide from the cell culture medium, as recited in claim 49, (see col. 3, lines 12-17). One of ordinary skill in the art at the time the invention was made would have been motivated to use the DNA taught by Korenberg in a method for expression of a DS-CAM related protein, in order to produce large quantities of the protein as taught in col. 3. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

15. The Applicants arguments concerning Korenberg, et al., have been discussed, *supra*. The Applicants also argue that there is no motivation to combine the teachings of Gallatin, et al. However, as discussed in the Paper No. 18, "one of ordinary skill in the art at the time the invention was made would have been motivated to use the DNA taught by Korenberg in a method for expression of a DS-CAM related protein, in order to produce large quantities of the protein as taught in col. 3."

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16. Claims 33-37 and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Genexpress cDNA Program (*GenBank, Accession # F13426*), in view of Gallatin, et al., (US Patent No. 5,525,487).
17. # F13426 has been discussed, *supra*. # F13426 does not teach or a method for expression of a DS-CAM related protein. However, the '487 patent teaches that in order to produce the polypeptide in large quantities, the host cells, can be used in a method of expressing the polypeptide then isolating the polypeptide from the cell culture medium, as recited in claim 49, (see col. 3, lines 12-17). One of ordinary skill in the art at the time the invention was made would have been motivated to use the DNA taught by # F13426 in a method for expression of a DS-CAM related protein, in order to produce large quantities of the protein as taught in col. 3. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.
18. The Applicants arguments concerning # F13426, have been discussed, *supra*. The Applicants also argue that there is no motivation to combine the teachings of Gallatin, et al. However, as discussed in the Paper No. 18, "one of ordinary skill in the art at the time the invention was made would have been motivated to use the DNA taught by Korenberg in a method for expression of a DS-CAM related protein, in order to produce large quantities of the protein as taught in col. 3." In response to Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Claim Rejections - 35 U.S.C. § 112

19. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20. Claims 33, 34, 36, 37, 47 and 48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is insufficient support in the specification for the recitation in claim 33 for "intronless". There is also insufficient support for the limitation in claim 34 for the recitation of hybridization to a second and third nucleic acid molecule. Applicants are invited to direct the Examiner to any support in the specification for these limitations. **This is a new matter rejection.**

Note: The Applicants assert in the paper filed 3/9/2001, Paper No. 24 that the range limitations are taught in Figure 2. The Examiner agrees that the range limitations in claim 34 are not new matter.

21. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

22. Claims 33, 36, 37, 47 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

23. The recitation in claim 33, whereby a nucleic acid molecule hybridizes to a second nucleic acid molecule. It is unclear from the claims and from Applicants' remarks in Paper No. 20, whether the Applicants intend to claim a nucleic acid molecule which hybridizes to 2 separate molecules concurrently, or whether the claim is drawn to a nucleic acid molecule which binds to a separate, second molecule. Clarification is required.

Allowable Subject Matter

24. Claims 44-46 are allowed. The prior art does not teach a nucleic acid sequence set forth in SEQ ID NOS: 5-8 or 10, which encodes SEQ ID NO: 11, 15 nucleotides or longer.

Conclusion

25. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.

26. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Tuesday through Friday from 8:30 am to 6:00

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pm, and on alternating Mondays. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

July 24, 2001

Mary B. Tung, Ph.D.
Patent Examiner
Group 1640

Mary B. Tung
MARY BETH TUNG, PH.D.
PATENT EXAMINER